

REMARKS

Upon entry of this amendment, claims 10, 12, 19, 21 24, and 26 will be pending and under examination. The subject matter of canceled claims 25 and 27 are now represented by the amended claims 10 and 12, respectively. Support for amendments can be found throughout the specification and in the original claims.

Applicants thank the Examiner for withdrawing the restriction requirement and examining all claims and all sequences depicted by SEQ ID NO: 2-7 together.

Claim Objections

The Examiner objects to claims 10 and 12 as encompassing non-elected subject matter. Applicants respectfully submit that, since the restriction requirement and election of sequences were withdrawn, all subject matter previously in the claims is being examined, and there is no non-elected subject matter. Furthermore, without prejudice and not in response to this rejection, subparts (c) through (g) have been deleted in the amended claims. Applicants respectfully request the Examiner withdraw this objection.

35 USC §112 First Paragraph

The Examiner rejected claims 10, 12, 19, 21 and 24-27 under 35 USC §112 first paragraph, alleging that the specification does not reasonably provide enablement for a method of preserving motor function in a mammal with symptoms or at risk of amyotrophic lateral sclerosis (ALS) and spinal cord injury. The Examiner concedes that the specification is enabling for inducing dendritic arbors, neurite outgrowth, and neuronal survival by OP-1. The Examiner also concedes that the specification enables enhancing neural development by OP-1 *in vivo*. However, the Examiner alleges that the complex and multiple elements of motor function that can be affected in ALS cannot all be addressed by administration of a morphogen alone.

While Applicants do not concede the correctness of the Examiner's position, Applicants amended the claims so that it is clearly indicated that a morphogen preserves the motor function by enhancing neural survival and, as described concretely in Examples 17 and 18, by enhancing formation of functional synapses. Applicants have described the activities of a morphogen in the specification as "preserving " and "maintaining" the neural pathway and its functions, each

providing particular functions. The claims are directed to the preservation of neural pathway involved in motor function.

The Examiner questions the adequacy of the disclosure of the specification regarding when a subject becomes at risk of ALS or spinal cord injury. Applicants believe one skilled in the art would easily recognize the meaning of a subject being at risk: for example, genetically disposed, or, having been diagnosed but asymptomatic of a disease. However, in the interest of advancing the prosecution, without conceding the correctness of the Examiner's interpretation, Applicants amended the claims without prejudice and no longer recite "at risk."

The Examiner also alleges that the specification does not provide sufficient guidance for morphogens other than OP-1. The claims have been amended to more clearly describe the proteins clearly structurally related to OP-1. In addition, Examiner alleges that a change of one amino acid residue may render a protein inactive from its original activity to illustrate the unknown nature of the claimed genus. Applicants recognize that a protein must be biologically active, and submits that the functional limitation already present in the claims is there for that reason.

Applicants respectfully direct the Examiner's attention to claims of patents already issued to Applicants and coinventors, for example, U.S. Pat. No. 6,565,843; 6,531,445; 6,194,376; 6,288,031; 6,077,823; 6,800,603; 6,407,060; 6,949,505; 6,498,142; 6,861,404; 6,090,776; 7,060,680; 5,674,522; 7,056,882; and the parent application of this instant application, which issued as 6,723,698. The claims of these patents all recite a morphogen analog with 70% homology or 60% identity to the seven-cysteine region of OP-1, and peptides having generic and other sequences related to OP-1. While Applicants are aware each application is examined independently, Applicants submit that these issued claims are presumed valid. As such, the burden is on the Examiner to establish that these claims are indeed not enabled. Applicants also would like to remind the Examiner that predictability and consistency is beneficial and necessary among related patents.

Without conceding to the correctness of the Examiner's remarks and not inconsistent with our statement above, the claims have been amended to more clearly describe the "conserved seven-cysteine skeleton" which is understood to contain the cysteines. Applicants have shown multiple morphogens that are species of the claimed genus share the ability to enhance dendritic

growth of sympathetic neurons, and survival of neurons (see, e.g., Tables III and IV). Further, incorporated by reference, artificial proteins COP-5, COP-7, etc. have been shown to possess characteristic activities exhibited by morphogens. Applicants respectfully submit that the experimental data for the number of examples provided by Applicants are more than sufficient to show the possession of the whole genus and to differentiate the members of the genus from related proteins that are not part of the genus, and that the claims are enabled.

Based on the amendment of the claims and for the reasons set forth above, Applicants submit that all reasons for rejections have been addressed and overcome. A favorable consideration is requested.

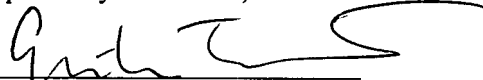
Obviousness-Type Double Patenting

Claims 10, 12, 19, 21, and 24-26 were also rejected as not patentably distinct from claims 1-16 of U.S. Pat. No. 6723698, and also provisionally rejected over claims 97, 99, 105-108, 112 and 113 of copending application No. 08/937,756 and claims 50 and 51 of copending application No. 10/865,514. Applicants will file a suitable terminal disclaimer when allowable subject matter is indicated.

Applicants believe no additional fee is due with this response. However, if a fee is due, please charge our Deposit Account No. 18-1945, under Order No. JJJ-P02-511 from which the undersigned is authorized to draw.

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Respectfully submitted,

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